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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/935,717	09/23/97	CATT	M 241939

HM32/0107

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EXAMINER

PORTNER, V

ART UNIT	PAPER NUMBER
1641	4

DATE MAILED: 01/07/99

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

## Office Action Summary

Application No.

08/35,717

Applicant(s)

Catt et al

Examiner

Portner

Group Art Unit

1641

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

☒ Responsive to communication(s) filed on Oct. 19, 1998

☒ This action is FINAL.

- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

☒ Claim(s) 4,5-10 is/are pending in the application.

Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 4,5-10 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
  - ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
  - ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
  - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other \_\_\_\_\_

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### **DETAILED ACTION**

Claims 1, 5-10 are pending.

#### ***Rejections Withdrawn***

1. Claims 1, 5-10 are no longer rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention in light of the Amendment of the claims on paper number 3, dated October 19, 1998.

#### ***Rejections Maintained***

2. Claims 1, 5-10 remain rejected under 35 U.S.C. 102(b) as being anticipated or in the alternative under 35 U.S.C. 103 obvious over Catt et al WO 95/13531 for reasons of record as applied to claims 1-10. It was noted that the original rejection did not specifically recite the statute for the obviousness rejection made but that the rejection did say "as being anticipated or in the alternative obvious over" and arguments with respect to obviousness were made of record on paper number 2. Therefore, the rejection which is being maintained over the claims is not considered by the examiner to be a new grounds of rejection.

3. Claims 1, 5-10 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Jina et al (US Pat. 5,526,120, filing date September 8, 1994) for reasons of record as applied to claims 1-10.

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4. *Response to Arguments*

5. Applicant argues that WO95/13531 does not disclose the claim limitations of claim 3 or 4 as now incorporated in the amended claim 1.

6. Applicant's arguments filed with respect to WO95/13531 have been fully considered but they are not persuasive because claim 13 of the cited reference teaches the limitations of claim 3 and the disclosure on page 22, paragraph 3 to page 23-line 37 does teach and disclose the device features of claim 4. Therefore, WO95/13531 teaches and suggests the now claimed invention.

7. With respect to Jina, it is asserted that Jina does not show the combination of features as define in claim 1 as amended.

8. Applicant's arguments filed with respect to Jina have been fully considered but they are not persuasive because Jina does disclose a test strip with an asymmetrical end which insures the correct insertion for measuring for an analyte in a liquid sample. The asymmetries combine to permit a test strip to be inserted into the apparatus when it is correctly aligned and is associated with circuitry when the strip is fully inserted. The test strip when fully inserted closes an electrical circuit, the closing of which is monitored by the apparatus and allows the determination of an analyte (see col. 4, lines 47-67 and col. 5, lines 1-48; abstract and figures) Jina teach that the device is useful in the determination of glucose, cholesterol and alcohol in human blood (col. 5,

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line 35). Jina differs from the instantly claimed invention by failing to show the formulation of the assay test strip and apparatus into kit form for the determination of one or more analytes.

9. Therefore, it would have been obvious to the person of ordinary skill in the art at the time the invention was made to determine one or more one analytes with the device of Jina because Jina discloses that the device is useful in the determination of more than one analyte and the person of ordinary skill in the art would have been motivated and would have had a reasonable expectation of success in obtaining test kits which would be able to determine one or more analytes in a sample of fluid because Jina teach devices and means for the evaluation of analytes and kits are an art recognized means for the convenient distribution of assay components to the desired end user for the determination of biologically significant analytes. If

applicants contend that this is not the case, applicants are advised that the Office does not have the facilities for examining and comparing applicant's product with the prior art, and that the burden is on applicant to show a novel or unobvious difference between the claimed method and the method of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA) and Ex parte Gray, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. and Int.)

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***Conclusion***

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (703)308-7543. The examiner can normally be reached on Monday through Friday from 7:30 AM to 5:00 PM except for the first Friday of each two week period.

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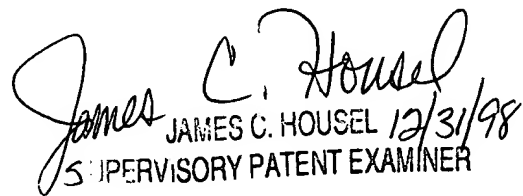
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for this group is (703) 305-7939.

The Group and/or Art Unit location of your application in the PTO will be changing February 7, 1998. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vgp

December 22, 1998

 JAMES C. HOUSEL 12/31/98  
SUPERVISORY PATENT EXAMINER